**Edition Date:** 2005-10-08 **Revision Date:** 2020-06-25

**Revised by:** Annette Roy, Regulatory

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Product Name: Micrewtube® | Catalogue No.: T338-2S

This document replaces any previous version

# 1. Product Description:

> **0.5ml Micrewtube**\*: Sterile, self-standing with lip seal screw cap.

Caps are screwed on.

2. Packaging:

Case: 10 packages of 50 units / 500 units per case

# 3. Product Specifications:

- Material:
  - Polypropylene tube;
  - Polyethylene cap.
- Certified RNase, DNase, Pyrogen and DNA Free;
- > Gamma radiation sterilized at a SAL of 10<sup>-3</sup>; specified dose between 6.5 kGy and 13.5 kGy;
- Temperature range: -196°C to +100°C;
- Tubes have white marking areas;
- Centrifuged up to 17 000 g.

## 4. Standards and Conformity:

ISO 2859-1: Sampling and inspection procedures
FDA: Resin conforms to FDA 21 CFR 177.1520

> USP: Resin conforms to USP Class VI

**CONEG / RoHS:** Plastics and colorants are in conformity with

CONEG / RoHS standards for heavy metals

REACH (SVHC): Plastic is in conformity to REACH standards

LATEX: Material is Latex FreeBSE / TSE: Material is BSE / TSE Free

## 5. Quality Assurance:

- Clear, no presence of contamination in plastic;
- Visual attributes:
- Volume measurements;
- Closure verification;
- Leak proof testing in vacuum at 71.3cm Hg;
- Gas phase of Liquid Nitrogen resistance.

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## 6. Traceability:

**Lot No. Composition:** 8 to 9 digits

#### > The lot number can be found in one or all of these locations:

- 1. On exterior case label;
- 2. On label inserted inside the master case;
- 3. On the inner bag.

## 7. Storage Conditions:

- Store at room temperature in normal warehouse conditions;
- Avoid temperature variations and humidity;
- Protect from any possible contamination;
- Protect from any damage to the packaging which could compromise the product sterility.

#### 8. Recommended Use:

- Verify proper cap closure when using biohazard material and / or chemical reagents;
- > Follow chemical resistance chart recommendations;
- For use in automated equipment, follow the equipment manufacturer's instructions;
- Should be used only in the gas phase of Liquid Nitrogen.

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